UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

BENJAMIN HENDRICKS,

Plaintiff,

v.

Civil Action 2:12-cv-00613
Judge George C. Smith
Magistrate Judge Elizabeth P. Deavers

PHARMACIA CORPORATION, *et al.*,

Defendants.

ORDER AND REPORT AND RECOMMENDATION

Plaintiff, Benjamin Hendricks, who is proceeding without the assistance of counsel, brings this diversity action against Defendants, Pharmacia Corporation, Pfizer, Inc., Pfizer Pharmaceuticals, LLC, and Warner Lambert Company ("Pfizer Defendants") and Mylan, Inc., formerly known as Mylan Laboratories, Inc., Mylan Bertek Pharmaceuticals, Inc., and Mylan Pharmaceuticals, Inc. ("Mylan Defendants"). Plaintiff asserts that he developed a severe skin condition after ingesting the generic form of the anti-seizure drug Dilantin®. This matter is before the Court on the Pfizer and Mylan Defendants' Motions to Dismiss (ECF Nos. 25 and 26), Plaintiff's Memorandum in Opposition (ECF No. 38), and Defendants' Replies (ECF Nos. 41 and 42). For the reasons that follow, the Undersigned **RECOMMENDS** that the Court **GRANT** Defendants' Motions to Dismiss**.**

I.

Plaintiff alleges the following facts in his Complaint. For the purpose of Defendants' Motions to Dismiss, they are accepted as true. Plaintiff is an inmate housed at the Frazier Health Center in Orient, Ohio. Plaintiff's physician prescribed him Phenytoin (Dilantin®), an anti-seizure medication, in October 2009. The Pfizer Defendants manufacture Dilantin®, the brand-

name version of the drug. The Mylan Defendants manufacture Phenytoin, the generic version.[1] After Plaintiff took Phenytoin, he developed a "skin rash that resulted in blisters to [his] face and body." (Compl. ¶ 29, ECF No. 7.) On October 10, 2009, Plaintiff was diagnosed with Stevens-Johnson Syndrome, a skin condition that resulted in "painful and permanent injuries." (*Id*. at ¶ 30.)

Plaintiff brings nine claims against Defendants as a result of his alleged adverse reaction to Phenytoin: (1) Failure to Warn; (2) Defective Design or Manufacture; (3) Deceit by Concealment; (4) Breach of Implied Warranty; (5) Negligence; (6) Gross Negligence; (7) Negligence *per se*; (8) Negligent Misrepresentation; and (9) Violation of Consumer Protection and Fraud Statutes. He alleges that his physician relied on Defendants' representations that Phenytoin was safe. Further, Plaintiff asserts that, if he had known of the risk of Stevens-Johnson Syndrome, he would not have taken Phenytoin.

In their Motions to Dismiss, Defendants assert that Plaintiff's causes of action are governed by the Ohio Product Liability Act ("OPLA"). Both Pfizer and the Mylan Defendants argue that Plaintiff's Complaint should be dismissed for failure to plead under the OPLA. Defendants further assert that, even if Plaintiff had properly pleaded under the OPLA, his factual assertions fail to state a claim upon which relief can be granted. The Pfizer Defendants argue that Plaintiff does not clarify in his Complaint that he received the brand-name version of the drug. The Mylan Defendants argue that Plaintiff's claims fail because, as to generic manufacturers, all of Plaintiff's causes of action are preempted by federal law.

[1] Plaintiff uses the terms "Phenytoin" and "Dilantin" interchangeably in his Complaint. For the purposes of this Report and Recommendation, the Undersigned will use the term "Phenytoin" to refer to the generic drug manufactured by the Mylan Defendants and "Dilantin®" to refer to the brand-name drug manufactured by the Pfizer Defendants.

In his Memorandum in Opposition to Motions to Dismiss, Plaintiff concedes that he received Phenytoin, the generic version of Dilantin®. (Pl.'s Mem. in Opp. 2, ECF No. 38.) He also requests a 45-day extension to file an amended complaint under the OPLA. Plaintiff asserts that, even under the OPLA, the Pfizer Defendants are liable for inadequately warning about the danger of Stevens-Johnsons Syndrome. Plaintiff further argues that the Mylan Defendants could have modified its warning label to reflect updated safety information, regardless of their status as generic drug manufacturers.

In their Reply, the Pfizer Defendants point to Plaintiff's concession that he took the generic version of the drug. They assert that under the OPLA, a manufacturer can only be held liable if the plaintiff actually used its product. They maintain that Plaintiff's argument that they can be held liable for the alleged inadequate warnings on the generic drug has been rejected by most courts.

In the Mylan Defendants' Reply, they assert that Plaintiff's claims against them are preempted by federal law. Further, the Mylan Defendants argue that Plaintiff's interpretation of relevant case law is incorrect. They maintain that Plaintiff's claims should be dismissed with prejudice.

II.

To survive a motion to dismiss for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a plaintiff must satisfy the basic federal pleading requirements set forth in Federal Rule of Civil Procedure 8(a). Under Rule 8(a)(2), a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Thus, Rule 8(a) "imposes legal *and* factual demands on the authors of

complaints." *16630 Southfield Ltd., P'Ship v. Flagstar Bank, F.S.B.*, 727 F.3d 502, 503 (6th Cir. 2013).

Although this pleading standard does not require "'detailed factual allegations,' . . . [a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action,'" is insufficient. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A complaint will not "suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). Instead, to survive a motion to dismiss for failure to state a claim under Rule 12(b)(6), "a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Id*. (quoting *Twombly*, 550 U.S. at 570). Facial plausibility is established "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "The plausibility of an inference depends on a host of considerations, including common sense and the strength of competing explanations for the defendant's conduct." *Flagstar Bank*, 727 F.3d at 504 (citations omitted).

Further, the Court holds *pro se* complaints "'to less stringent standards than formal pleadings drafted by lawyers.'" *Garrett v. Belmont Cnty. Sheriff's Dep't.*, No. 08-3978, 2010 WL 1252923, at *2 (6th Cir. April 1, 2010) (quoting *Haines v. Kerner*, 404 U.S. 519, 520 (1972)). This lenient treatment, however, has limits; "'courts should not have to guess at the nature of the claim asserted.'" *Frengler v. Gen. Motors*, 482 F. App'x 975, 976-77 (6th Cir. 2012) (quoting *Wells v. Brown*, 891 F.2d 591, 594 (6th Cir. 1989)).

III.

All parties concede that Ohio law governs this diversity action. *See Muncie Power Prod., Inc. v. United Techs. Auto.*, 328 F.3d 870, 873 (6th Cir. 2003) (summarizing that, where Ohio is

the forum state, federal courts sitting in diversity apply a balancing test which presumes that "the law of the place where the injury occurs will be applied to a tort action" unless "another state has a more significant relationship to the action."); *Hogue v. Pfizer, Inc.*, 893 F. Supp. 2d 914, 916 (N.D. Ohio 2009) (concluding that Ohio law governed the action because plaintiff's alleged injuries occurred in Ohio) (citing *Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 917 (N.D. Ohio 2009) (in a personal injury action, Ohio "applies a balancing test . . . which presumes that the location of the injury controls the applicable law unless another state has a more significant relationship to the occurrence and parties."). Here, Plaintiff's alleged injuries occurred in Orient, Ohio.

A. OPLA

The OPLA, codified at Ohio Revised Code §§ 2307.71 to 2307.80, "explicitly eliminate[s] 'all common law product liability claims or causes of action.'" *Wimbush v. Wyeth*, 619 F.3d 632, 639 (6th Cir. 2010) (quoting Ohio Rev. Code § 2307.71(B)). The OPLA "applies to any recovery of compensatory, punitive, or exemplary damages based on a product liability claim." *Tolliver v. Bristol-Myers Squibb, Co.*, No. 1:12 CV 00754, 2012 WL 3074538, at *2 (N.D. Ohio July 30, 2012). "The statute defines a 'product liability claim' as one 'that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question' allegedly resulting from a manufacturing or design defect, inadequate warning, or nonconformance with manufacturer representations." *Id.* (quoting Ohio Rev. Code § 2307.71(A)(13)). The OPLA "covers injuries resulting from the use of an 'ethical drug[ ],' defined as 'a prescription drug that is prescribed or dispensed by a physician or any other person

who is legally authorized to prescribe or dispense a prescription drug.'" *Id.* (quoting Ohio Rev. Code § 2307.71(A)(4)).

The OPLA is the exclusive remedy for all of Plaintiff's claims. As set forth above, Plaintiff's claims relate to alleged adverse effects he suffered after ingesting the anti-seizure drug Phenytoin. The parties do not dispute that Phenytoin is a prescription drug that a licensed Physician provided to Plaintiff. Plaintiff seeks compensatory damages for, among other things, physical pain and suffering, emotional distress, physical damage, loss of consortium, and exemplary damages.[2] (Compl. ¶¶ 122-125, ECF No. 7.)

1. Common Law Claims

Plaintiff brings claims of common law failure to warn, defect in design or manufacture, breach of implied warranty, negligence, gross negligence, negligence *per se*, and negligent misrepresentation. These common law claims have all been abrogated by the OPLA. *See Hempy v. Breg, Inc.*, No. 2:11-CV-900, 2012 WL 380119 at *3 (S.D. Ohio Feb. 6, 2012) (concluding that claims for negligence and breach of warranty constitute common law product liability claims); *Bowles v. Novartis Pharm. Corp.*, No. 3:12-cv-145, 2013 WL 5297257, at *7 (S.D. Ohio Sept. 19, 2013) (concluding that claims for negligent manufacture and negligent failure to warn were subject to the OPLA); *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 943 (S.D. Ohio 2010) ("Further, common law warranty claims have also been abrogated by the OPLA. . . ."); *Miles*, 612 F. Supp. 2d at 924 (concluding that "implied warranty claims (both merchantability and fitness for a particular purpose) . . . constitute common law products liability claims subject to preemption by the OPLA.").

[2] In the interest of liberally construing Plaintiff's Complaint, the Undersigned will construe Plaintiff's citation of "Missouri law" in his request for exemplary damages as a typographical error which should refer to Ohio law. (Compl. ¶ 125, ECF No. 7.)

2. Fraud

To the extent Plaintiff's "deceit by concealment" claim is intended to be a claim for fraud, it is fully governed by the OPLA. In his Complaint, Plaintiff suggests that Defendants "deliberately and intentionally . . . concealed material facts from [] consumers" relating to the potential adverse effects of Dilantin® and Phenytoin. (Compl. ¶ 65, ECF No. 7.) "[T]he OPLA does not abrogate fraud claims which are based on a general duty not to actively deceive; however the OPLA does abrogate fraud claims arising from a duty to warn." *Hogue*, 893 F. Supp. 2d at 918 (citing *Stratford v. SmithKline Beecham Corp.*, No. 2:07-cv-639, 2008 WL 2491965, at *8 (S.D. Ohio June 17, 2008)). Plaintiff's assertion that Defendants concealed and omitted facts is essentially a claim for failure to warn. *Stratford*, 2008 WL 2491965 at *8 (holding that allegations of fraudulent omissions were "essentially allegations that [Defendant] failed to properly warn physicians and consumers of the risk" of the drug at issue and were thus preempted by the OPLA). Thus, Plaintiff's claims that Defendants concealed information about drug safety arise in failure to warn and are abrogated by the OPLA.

Plaintiff also maintains that Defendants "made misrepresentations of material facts . . . in the advertising, marketing, distribution and sale" of Phenytoin. (Compl. ¶ 64, ECF No. 7.) His contention that Defendants actively misrepresented the safety of Phenytoin presents a closer case for active fraud. Plaintiff's allegation, however, still falls under a failure to warn theory. *See Stratford*, 2008 WL 2491965 at *8 ("The claims of active misrepresentation are not necessarily abrogated by the OPLA because they may implicate the more general duty not to deceive, rather than the duty to warn."); *Hogue*, 893 F.Supp.2d at 917 (holding that the OPLA abrogated the plaintiff's claims where she alleged that defendants "disseminated false and misleading information which gives rise to claims under common law theories of fraud and negligent

misrepresentation."); *Blake v. Interneuron Pharm.*, No. C-1-98-672, 1998 WL 35307753, at *1 (S.D. Ohio Dec. 9, 1998) (holding that the plaintiff's claim that she was induced to use a drug "through the use of false and/or misleading advertising, representations, and statements" fell within the "expansive" OPLA). Here, Plaintiff's claims do not implicate Defendants' general duty not to deceive. Instead, they focus on Defendants' failure to warn Plaintiff's prescribing physician about the alleged risks of Phenytoin. Thus, Plaintiff's claim is abrogated by the OPLA.

3. Statutory Claim (Ohio Consumer Sales Practices Act)

Plaintiff's statutory claim is also abrogated by the OPLA. In his Ninth Claim, Plaintiff asserts that Defendants violated "consumer protection and fraud statutes" by making "misleading statements" about the risks of Phenytoin. (Compl. ¶¶ 115-119, ECF No. 7.) To the extent that Plaintiff is referring to the Ohio Consumer Sales Practices Act ("OCSPA"), the OPLA preempts such actions "where the OCSPA claims are primarily rooted in product liability claims." *Mitchell v. Proctor & Gamble*, No. 2:08-CV-426, 2010 WL 728222, at *4 (S.D. Ohio Mar. 1, 2010); *see also Schnell v. American Home Prod. Corp.*, No. 3:00 CV 7228, 2000 WL 35777837, at *1 (N.D. Ohio July 11, 2000) (concluding that the plaintiff's claims under the OCSPA were "encompassed under the statutory framework of the [OPLA]" because they alleged "representations[s] of a material fact concerning the character, quality, or safety of a product.") Here, Plaintiff contends that Defendants' conduct breached the consumer protection and fraud statutes by "representing to Plaintiff that Dilantin did not have a serious risk of injury or death and was otherwise safe, fit, and effective for human consumption . . ." (Compl. ¶ 118, ECF No. 7.) These matters, no matter how Plaintiff characterizes them, are not simply ordinary consumer

sales claims. Plaintiff's statutory claim is therefore rooted in product liability, specifically a claim for inadequate warning, which is preempted by the OPLA.

Here, Plaintiff pleaded nine theories of liability, none of which were pleaded under the OPLA. The Court could dismiss Plaintiff's claims for failing to plead with reference to the OPLA. *See, e.g., Stratford*, 2008 WL 2591965 at *5 ("Claims that are authorized by the OPLA should be pled with reference to the applicable provision of the OPLA.") Because Plaintiff is *pro se*, however, the Undersigned will construe his Complaint liberally. *See Haines v. Kerner*, 404 U.S. 519, 520-21 (1972) (concluding that allegations in a *pro se* complaint must be held to less stringent standards than those of "formal pleadings drafted by lawyers"). The Undersigned will therefore consider Plaintiff's claims as if he had pleaded them under the OPLA.

B. Pfizer Defendants

The Court may readily dispose of Plaintiff's claims against the Pfizer Defendants because Plaintiff concedes he never ingested the brand name version of the drug. The Undersigned concludes that Plaintiff's Complaint fails to state a claim for relief against the Pfizer Defendants. As noted above, the parties stipulate that Plaintiff never ingested Dilantin®. Plaintiff concedes that he "was not provided with the name brand drug Dilantin." (Pl.'s Mem. in Opp. 2, ECF No. 38.) He ingested only the generic version, Phenytoin, which Pfizer did not manufacture. The OPLA provides in relevant part as follows:

> Proof that a manufacturer designed, formulated, produced, constructed, created, assembled, or rebuilt the type of product in question is not proof that that manufacturer designed, formulated, produced, constructed, created, assembled, or rebuilt the actual defective product in the product liability claim. A manufacturer may not be held liable in a product liability action based on market share, enterprise, or industrywide liability.

Ohio Rev. Code § 2307.73(C). As addressed above, despite Plaintiff's failure to plead his claims under the OPLA, Plaintiff's claims are governed by the statute. *See Miles*, 612 F. Supp. 2d at 921 ("Under Ohio law it is the substance of the claim, not the manner in which it is pleaded, that determines how it is treated.") Under the OPLA, a manufacturer may not be held liable in a product liability action when the plaintiff did not use its product.

Plaintiff's argument that the Pfizer Defendants should be held liable based on the theory of innovator-liability is not well taken. Plaintiff contends that the Pfizer Defendants should be held liable for their failure to warn the Mylan Defendants of the risks of Dilantin. Courts have uniformly rejected this theory of holding a brand manufacturer liable for failing to warn a generic manufacturer. *Hogue*, 893 F.Supp.2d at 918-19 (holding that "the OPLA precludes [plaintiff's] argument that the Brand Manufacturers are subject to liability as inventors or primary manufacturers of metoclopramide as neither theory is an exception to the rule that a plaintiff must prove [his or] her injuries were caused by the actual product the defendant manufactured."); *In re Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.*, 856 F.Supp. 2d 904, 908 (E.D. Ky. 2012) (holding that, under Ohio law, a defendant cannot be held liable for an injury caused by a "a product that it did not sell, manufacture, or otherwise supply to the plaintiff" and "in the context of product liability claims, a plaintiff must state sufficient allegations to allow at least the reasonable inference that the product that caused the injury was made, sold, or distributed by the defendant in question.").

Plaintiff did not take a product made, sold, or distributed by the Pfizer Defendants. Thus, he cannot state a claim for which relief could be granted under the OPLA against the Pfizer Defendants. Accordingly, the Undersigned **RECOMMENDS** that the Court **DISMISS** Plaintiff's claims against the Pfizer Defendants**.**

C. Mylan Defendants

1. Failure to Warn, Deceit by Concealment, Negligence, and Consumer Protection and Fraud Statute

As addressed above, Plaintiff's claims of Deceit by Concealment, Negligence, Gross Negligence, Negligence *per se*, Negligent Misrepresentation, and violations of the Consumer Protection and Fraud Statute all sound in failure to warn under the OPLA. To be sure, throughout his Complaint, Plaintiff asserts that "Defendants failed to warn the public" about the dangers of Phenytoin or "concealed material facts" regarding the safety of its use. (Compl. ¶¶ 45, 64, 77, 84, 93, 110, and 118.)

Ohio Revised Code § 2307.76 governs liability based on "products defective due to inadequate warning or instruction." Ohio Rev. Code § 2307.76. In his Complaint, Plaintiff alleges that Defendants knew that Dilantin® and/or Phenytoin was defective because it caused adverse effects such as Stevens-Johnson Syndrome. He asserts that the Defendants failed to provide proper warning to his prescribing physician about the potential adverse effects associated with the drug. According to Plaintiff, his prescribing physician then relied on Defendants' representations. Plaintiff, therefore, maintains that his injuries were a direct and proximate result of Defendants' failure to warn. (Compl. ¶ 41-47, ECF No. 7.) The Mylan Defendants counter that they are required under federal law to have the same warning labels as their brand-name counterparts.

The United States Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011) "narrowed the scope for state failure-to-warn claims against generic drug manufacturers." *Fulgenzi v. PLIVA*, 711 F.3d 578, 581 (6th Cir. 2013). In *Mensing*, the plaintiffs brought state law failure to warn claims against generic drug manufacturers. The defendants argued that it

was impossible to comply with state law, which would have required them to change their warning labels, while at the same time comply with federal law, which required them to have the same warning labels as their brand-name counterparts. Noting that "[w]here state and federal law directly conflict, state law must give way," the Supreme Court first addressed the state products-liability laws at issue. *Id.* at 2577 (internal citations omitted). The Supreme Court noted that the relevant state laws "require a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe." *Id.* at 2573. Next, the Court considered the relevant federal law under the Food, Drug, and Cosmetic Act ("FDCA"):

> A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's . . . . The FDA . . . tells us that it interprets its regulations to require the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'

Id. at 2574-75. The Supreme Court concluded that it was impossible for the defendants to comply with both state and federal law. *Id.*; *see also Mutual Pharm. Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 2469 (2013) ("But *PLIVA* makes clear that federal law prevents generic drug manufacturers from changing their labels").

The Mylan Defendants argue that the same impossibility exists under Ohio law. The OPLA states in relevant part as follows:

> (A) Subject to divisions (B) and (C) of this section, a product is defective due to inadequate warning or instruction if either of the following applies:
>
> (1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code. § 2307.76(A). The Mylan Defendants note that "When Plaintiff's treating physician prescribed [P]henytoin to him, Mylan was in compliance with federal law" because the FDA-approved warning label was the same as the brand-name warning label. (Defs.' Mem. in Opp. 8, ECF No. 25.) Plaintiff does not assert that the Mylan Defendants failed to include language contained in the brand-name warning label. *See, e.g.*, *Fulgenzi*, 711 F.3d at 584 (noting that the plaintiff's failure to warn claims against a generic manufacturer survived only to the extent the plaintiff argued that the generic manufacturer failed to include updated brand-name warning language). Instead, Plaintiff broadly argues without more that both the brand-name and generic manufacturers failed to provide appropriate warnings about the risk of Stevens-Johnson Syndrome.

The Mylan Defendants' arguments are well taken. As the case law makes clear, as generic drug manufacturers Mylan had a duty of "sameness." Mylan may not be held liable failing to change their warning label when it was the same as the brand-name label. Plaintiff does not allege that the Mylan Defendants' warning label differed from the brand-name warning. Accordingly, the Undersigned **RECOMMENDS** that the Court **DISMISS** Plaintiff's Failure to Warn, Deceit by Concealment, Negligence, Gross Negligence, Negligence *per se*, Negligent

Misrepresentation, and Consumer Protection and Fraud Statute claims against the Mylan Defendants**.**

2. Breach of Implied Warranty

Plaintiff has also failed to state a claim under the OPLA for breach of implied warranty. "The 'OPLA has preempted the implied warranty of merchantability and the implied warranty of fitness for a particular purpose.'" *Stratford*, 2008 WL 2491965 at *7 (citing *Luthman v. Minister Supply Co.*, 2008 Ohio 165 (Ohio Ct. App. Jan. 22, 2008)); *see also Miles*, 612 F. Supp. 2d at 923-24 (concluding that "the unambiguous statutory language, which covers 'any relevant . . . warranty,' clearly covers implied warranties as well as express") (citing Ohio Rev. Code § 2307.71(A)(13(c)). "Ohio Revised Code § 2307.74 describes a statutory cause of action for a product that is 'defective in manufacture and construction' which has common elements with the common law implied warranty/strict tort liability cause of action." *Stratford*, 2008 WL 2491965 at *7. This provision "requires that the plaintiff show that the product 'deviated in a material way from the design specifications, formula, or performance standards of the manufacturer.'" *Id.* (citing Ohio Rev. Code 2307.74).

Here, Plaintiff's Complaint merely alleges that "Defendants' product Dilantin was not of merchantable quality and was not safe or fit for its intended use." (Compl. ¶ 78, ECF No. 7.) His Complaint contains no factual allegations to support these conclusory statements. Even construing the Complaint in the light most favorable to Plaintiff, the Court is not required to accept these bare legal conclusions as true. *Iqbal*, 129 S.Ct. at 1949. Finally, to the extent that Plaintiff alleges the Mylan Defendants breached an implied warranty by failing to warn about the risk of Stevens-Johnson Syndrome, his claim fails for the preemption reasons addressed above.

The Undersigned therefore **RECOMMENDS** that the Court **DISMISS** Plaintiff's claim of Breach of Implied Warranty.

3. Defect in Design or Manufacture

Plaintiff's only remaining claim is one for defect in the design or manufacture of Phenytoin. "The OPLA recognizes a design or defect claim 'if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation.'" *Tolliver*, 2012 WL 30745 at *4 (quoting Ohio Rev. Code § 2307.75(A)). Put another way, "[t]o succeed on a manufacturing defect claim under the OPLA, a plaintiff must show that '(1) there was, in fact, a defect in the product manufactured and sold by the defendant; (2) such defect existed at the time the product left the hands of the defendant; and (3) the defect was the direct and proximate cause of the plaintiffs' injuries or loss.'" *Id*. at * 3 (quoting *Saraney v. TAP Pharm. Prods., Inc.*, No. 1:04-CV02026, 2007 Wl 148845, at *7 (N.D. Ohio Jan. 16, 2007)).

Plaintiff fails to state a design or manufacturing defect claim. Plaintiff fails to allege how Phenytoin was defective or how the defect was the proximate cause of his injuries. He merely asserts in a conclusory manner that:

> The product Dilantin manufactured, supplied, and/or sold by Defendants was defective in design or formulation in that when it left the hands of the manufacturers and/or sellers and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with the designs or formulations of the product.

(Compl. ¶ 52, ECF No. 7.) Further, Plaintiff simply notes that the alleged design or manufacturing defect was the proximate cause of his injuries. Such conclusory pleadings will not survive a motion to dismiss. *See Mills v. Bristol-Myers Squibb Co.*, No. CV 11-968-PHX-FJM, 2011 WL 3566131, at *2 (D. Ariz. Aug. 12, 2011) (noting that plaintiff's assertion that a

drug was defective because it caused her injuries within a few days after taking it did not "allege how the product itself is defective, it only alleges the harm plaintiff suffered after taking [the drug]."); *Tolliver*, 2012 WL 3074538 at *3 (dismissing plaintiff's defect in design or manufacture claim where plaintiff failed to provide a causal relationship between his taking the drug and his resulting medical problems). Moreover, to the extent Plaintiff asserts that the Mylan Defendants had a duty to make changes to Phenytoin's design in order to make it safer, such changes are prohibited by federal law. *See Mutual Pharm.*, 133 S.Ct. 2466 at 2475 (concluding that a generic drug manufacturer could not redesign the formulation of the drug because "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based.").

Accordingly, the Undersigned **RECOMMENDS** that the Court **DISMISS** Plaintiff's claim for Defect in Design or Manufacture.

D. Request for Leave to Amend

In his Memorandum in Opposition to Defendants' Motions to Dismiss, Plaintiff requests a 45-day extension to file an amended complaint under the OPLA. "The grounds for such a request, however, should be stated with particularity in a motion to the court." *Tolliver*, 2012 WL 3074538 at *5 (denying plaintiff's one-line request to amend his complaint in response to defendants' motion to dismiss); s*ee also Evans v. Pearson Enters., Inc.*, 434 F.3d 839, 852 (6th Cir. 2003) (concluding that the district court did not abuse its discretion in denying plaintiff's request for leave to amend where plaintiff "failed to state the grounds for relief with particularity" and did not present the request as a distinct motion); *Begala v. PNC Bank, Ohio, Nat'l Ass'n*, 214 F.3d 776, 784 (6th Cir. 2000) ("What plaintiffs may have stated, almost as an

aside, to the district court in a memorandum in opposition to defendant's motion to dismiss is . . . not a motion to amend."). Plaintiff's request is not presented as a separate motion. Moreover, Plaintiff's request is not stated with particularity. As best the Undersigned can discern, however, Plaintiff would like to amend his Complaint to defeat a dismissal for failing to plead under the OPLA. Because Plaintiff has not properly moved to amend his Complaint, and because the Court has construed Plaintiff's Complaint under the provisions of the OPLA, his request to amend his Complaint is **DENIED**.

IV.

For the reasons set forth above, it is **RECOMMENDED** that the Defendants' Motions to Dismiss be **GRANTED**. (ECF Nos. 24 and 26.) Plaintiff's request to amend his Complaint is **DENIED**.

V. PROCEDURE FOR OBJECTIONS

If any party seeks review by the District Judge of this Report and Recommendation, that party may, within fourteen (14) days, file and serve on all parties objections to the Report and Recommendation, specifically designating this Report and Recommendation, and the part in question, as well as the basis for objection. 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b). Response to objections must be filed within fourteen (14) days after being served with a copy. Fed. R. Civ. P. 72(b).

The parties are specifically advised that the failure to object to the Report and Recommendation will result in a waiver of the right to *de novo* review by the District Judge and waiver of the right to appeal the judgment of the District Court. *See, e.g., Pfahler v. Nat'l Latex Prod. Co.*, 517 F.3d 816, 829 (6th Cir. 2007) (holding that "failure to object to the magistrate judge's recommendations constituted a waiver of [the defendant's] ability to appeal the district

court's ruling"); *United States v. Sullivan*, 431 F.3d 976, 984 (6th Cir. 2005) (holding that defendant waived appeal of district court's denial of pretrial motion by failing to timely object to magistrate judge's report and recommendation). Even when timely objections are filed, appellate review of issues not raised in those objections is waived. *Robert v. Tesson*, 507 F.3d 981, 994 (6th Cir. 2007) ("[A] general objection to a magistrate judge's report, which fails to specify the issues of contention, does not suffice to preserve an issue for appeal . . . .") (citation omitted)).

Date: June 4, 2014

/s/ *Elizabeth A. Preston Deavers*
Elizabeth A. Preston Deavers
United States Magistrate Judge